IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	: 10/541,087	Confirmation No.	4064
Applicant	: Norbert Mencke		
Filed	: April 10, 2006		
Title	: METHOD OF REPELLING ARTHROPODS		
Group Art Unit	: 1616		
Examiner	: DANIELLE D SULLIVAN		
Docket No.	: LeA 36544		

VIA EFS

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. §1.132

Dr. Andreas Turberg, declares and states as follows:

1. I am one of the named CO-inventors of the subject matter of the above identified patent application.

2. I received a Master of Science degree in Biology from Heinrich-Heine University Dusseldorf, in 1986. Thereafter, I received a PhD from Heinrich-Heine University Dusseldorf in 1990. Main topics of my university education have been biochemistry and molecular biology applied in the fields of parasitology, entomology and pesticide chemistry.

3. In 1992 I started my career as a biologist at Bayer AG. From 1992 to date, I have been employed in the department of parasitology in the Animal Health Division first of Bayer AG, Germany and - due to the reorganizations of the Bayer group - since 2003 of Bayer Healthcare AG and since 2008 of Bayer Animal Health GmbH, Monheim, Germany. My

present position is Manager of Laboratory Arthropodicide Research in the Department of Parasitology.

4. I have evaluated the Snyder Patent, US 6,603,771, and Sembo, US Patent 6201017, as an expert in the area of ectoparasites.

5. Sembo does not define the term control/controlling. Snyder correctly describes / defines the term "control of lice infestation" as it would be read by one skilled in the relevant art. The term control in a medical sense of parasite control consists of two potential means to achieve such control: 1) TREATMENT of existing parasite populations and 2) PREVENTING a re-infestation (re-establishment of a parasite population on-host). TREATMENT of existing parasite populations is recognized by one skilled in the relevant art as therapeutic efficacy. PREVENTING is recognized by one skilled in the relevant art as prophylactic efficacy.

6. Though both such terms are not used in neither Snyder nor Sembo these are obvious synonyms for one skilled in the relevant art.

7. This can also be revealed through definition search i.e. on www.miriam-webster.com where the term preventative has to be read as its medical meaning as "defending against disease" with prompting synonyms like preventive, prophylactic, protective.

8. Thus as one skilled in the relevant art I would not equal "preventing" or "repelling". In the context of the publication I would always read treatment and prevention as its medical term (as set out above) where an obvious repellency cannot be concluded from.

9. As a preventative one skilled in the relevant art would see the goal of the treatment as to create conditions on host that would not allow for a new

lice population to establish. Means to achieve preventing new lice populations to be established are multiple. The residual activity certainly can kill any adult lice arriving on the host. It may also kill developing stages arriving on the host. Ultimately, it may break the cycle in killing developing stages in the eggs before hatching. Actually such ovicidal activity has been emphasized by Snyder.

10. Snyder in his publication did not mention anything about repellency in connection with his invention. On the contrary, the experimental design in example 9 leads away from a potential repellent idea with activity measured to start after 1 hour while repellent effects set in within seconds or at least minutes. Furthermore, the experiment dealt with dipping in a detergent containing aqueous dilution of a spinosyn. That showed efficacy (mortality) upon immersion of lice above 90% after one hour but there was no mentioning of repellency (lice trying to escape the solution). The experiment does not demonstrate repellency only some speed of kill in the highest dose.

11. Snyder also remains ambivalent concerning the use of other compounds (including pyrethroids) in combination. Column 2 / line 2-9 clearly states the disadvantages of the listed compounds known to be active against lice leading away from the use of such combinations, though it is later on not excluded (column 4 /line 9/10). However, the following formulation and biological examples (columns 15-19) clearly demonstrate the intention of the inventors to use spinosyns alone. No combinations with other compounds are listed as examples.

12. The main effect of the formulations that can be learned from the publication by one skilled in the relevant art is a therapeutic effect on lice by killing the population by immersion in a formulation containing a spinosyn.

13. Snyder put special emphasis on the importance to kill all stages including lice eggs (column 1 / line 60). The good efficacy on developmental stages by spinosyns is known from US5362634 and US5591606, summarized by Copping et al (Pest Management Science (2000), 56, 651–676) and Peterson et al (Down to Earth (1998), 53, 22–25). None of the review literature at that time or nowadays links spinosyns to repellent effects.

14. Thus the residual effect of the compound - assuming the presence of prophylactic efficacy (which has not been proven in the publication of Snyder) – would be for the one skilled in the relevant art based on the effect on eggs (following column 4 / line 13) or developmental stages thus preventing a new lice population to establish on host but certainly not teaching repellency.

15. Sembo teaches pest repelling compounds on column 6, line 67 to column 7, line 5, however, pyrethroids are not included in the pest repelling compounds. Pyrethroids are only included in the list of active ingredients not as pest repelling compounds.

16. The applicant further declares that all statements made herein are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application or any patent issuing therefrom.

Dr. Andreas Turberg

Date